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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,318	07/17/2000	David N Roundhill	500789.01	9061

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT PAPER NUMBER

3737

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,318

Applicant(s)

ROUNDHILL ET AL.

Examiner

Jaworski Francis J.

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-107 is/are pending in the application.
- 4a) Of the above claim(s) 59-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 32, 33, 35-39, 42-46, 48, 50-55, 58, 71, 73-82, 84-92 and 95-107 is/are rejected.
- 7) ☒ Claim(s) 31, 34, 40, 41, 47, 49, 56, 57, 72, 83, 93 and 94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

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1. Claims 1 - 27 have been cancelled. Claims 59-70 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.
2. Rule 126 renumbering remains in effect such that the second numbered claim 70 has been re-numbered as "71" et sequitur.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 28-30, 32-33, 35-39, 42-46, 48, 50-55, 58, 71, 73-82, 84-92, 95-107 are rejected under 35 U.S.C. 103(a) as being obvious over Ishibashi et al (US5984881 filed March 29, 1996) alone or further in view of Hassler et al. (See the Response portion below.)
5. Ishibashi et al teaches apparatus and method for an ultrasound imaging system used in conjunction with ultrasound therapy in a non-contrast agent setting for producing a three-dimensional image (col.20 lines 23 - 46), the system comprising an ultrasound transducer (16 and possibly also 2), an ultrasound transmitter 17 coupled to the transducer, the transducer being operable to generate a signal having a fundamental frequency (col. 10 lines 40-45 in consideration of 'mode B' operation col. 11 line 60 - col. 12 line 58), a receiver and beamformer 19, 20 coupled to the transducer 16 for depth-dependent reception, a filter (Fig. 2 and attendant passage col. 11 lines 34-49) including an operability to pass

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signals at f2 which are a harmonic of the fundamental f1 (col. 10 lines 4-5 vs col. 10 line 66 - col. 11 line 4, or as supplemented by the italicized statement below), and an image processor 22 (col. 11 lines 20 - 26) operable to generate a three-dimensional image from the output of the filter.

6. Ishibashi et al additionally teaches a Fig. 7 embodiment with generally corresponding parts save that probe 16 is configured to serve an additional filter function (per col. 14 lines 61 - 65) and also an echo filter 54 for this purpose is used (col. 15 lines 23-28) and *explicit teaching is made in col. 15 lines 1-32 that the display product may therefore be a function of the fundamental or harmonic (interpreted to embrace switching therebetween) or both (Summation suggestion, also interpreted to be a 'blend' -claim 89- since additionally the intensity distribution is overlaid or superimposed on the anatomic image.). An additional reference to the fact that harmonics are being analyzed occurs in relation to the fourth embodiment col. 18 lines 46-51 otherwise directed to operation of a doppler artifact filter. Alternative still to these concepts, col. 20 lines 1-20 teaches that in the evaluation of intensity distribution itself, harmonics of the f1 fundamental appear which can serve to mark the heating focus by the non-linear intensity effect, and it is in this latter context that the aforementioned later- col. 20 passage relates to three-dimensional imaging.*

7. A Doppler processor is selectively operable in all the various embodiments (claims 36-38, 52-54, 78-80, 84-86). And the filtering includes a frequency shift per Col. 30 lines 20-55 (claims 39, 55). Ordinary depth -dependent compensation as well as equalization filtering applies.(claims 32, 48).

8. With respect to claims 76, 77, 90-92, 101-102 in contradistinction to objected-to claim 47 directed to a similar feature, the claim is reasonably met dependent upon where the intensity distribution overlays onto the anatomic image since this determines in turn where the predominantly fundamental and predominantly harmonic components populate the display. Additionally the Fig. 12 embodiment for example relates to moving the focal point (intensity distribution image component) which therefore moves the 'blend' site.

9. With respect to claims 103-107 the U.S. 5928151 patent claims are rejected by the arguments as detailed above. For example claim 105 (originally 104 prior to re-numbering) is groupable with the Doppler arguments supra, claim

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106 (105) is groupable with the 'blending' argument supra, claim 107 by display superposition of Ishibashi et al's frequency analyzer outputs.

10. Claims 31, 34, 40-41, 47, 49, 56-57, 72, 83 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claim 94 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Amendment Arguments

Ishibashi et al make clear that in the prior art, the production of a tissue energy intensity distribution image in overlay registry with a locator or B-mode image involved under one option the receipt of both the therapy transducer pulse and the imager pulse at the same time, with the deficiency that the therapy transducer echo signal (in essence a harmonic) received by the imager was of low sensitivity. Due to the simultaneous receipt there could be no sensitivity compensation. Under another even less desirable option the two signals are received in alternation whereupon sensitivity could be adjusted but frame rate diminished and time resolution degraded to unacceptable levels by the alternation.

In this context it becomes clear that Ishibashi et al col. 12 is discussing re-visiting the 'combined therapy/imager pulse option' both by using ultrasonic dish (array) 2 and fine array 16 as a unitary f1, f2 transmitter with appropriate lag delay for the offset geometry and by using the broadband f1 and f2 sensitivity of the imaging transducers on the receive side. The discussion makes clear that the non-linearity (harmonics) of the therapy wave portion are received with more sensitivity by this approach, hence the therapy transducer need not be over-driven beyond a point to enhance this non-linearity such that tissue destruction will begin to occur.

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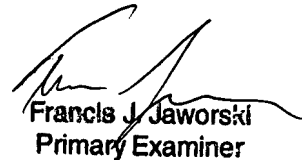
Such an imaging/tissue intensity distribution hybrid mode is fairly characterizable as bona fide hybrid imaging with respect to the intensity distribution transmitted portion or fl. This interpretive view is consistent with col. 15 lines 14-22 which states in effect that the intensity distribution image (which is an anatomic image albeit not necessarily the same as the tomographic image since the coincidence of both is being iteratively sought) may be filtered for in the FFT spectrum analyzer as to the fundamental or harmonic or both. As col. 20 lines 1-67 note, the harmonics are particularly of interest since the pressure non-linearity build-up is occurring where the heating is occurring. A three-dimensional such image logically is to be sought since tumor extent is three-dimensional as must be focussing of thermal therapy therefore.

Hassler et al Fig. 2 is included in the argument to the extent that since the specification col. 1 line 28 and col. 9 lines 37-43 make clear that lithotripter ultrasound is closely linked to diathermy for purposes of the Ishibashi et al disclosure, it would have been obvious in view of Hassler et al Fig. 2 for Ishibashi et al to make the imaging and therapy probe (broadband) structure one and the same integral array structure since the lag geometry is mitigated, whereupon the claim language demands regarding a 'transducer' if interpreted to pertain to a unit are more precisely met.

This action is not made final however the case should be prepared for final action.

Applicants' counsel is cordially invited to contact the Examiner to resolve patentability matters in this case.

Any inquiry concerning this communication should be directed to Examiner Francis J. Jaworski at telephone number 703-308-3061.



Francis J. Jaworski
Primary Examiner

FJJ:fjj

11-13-02